UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL PHARMACEUTICAL ALLIANCE, *et al.*,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 99-0394 (JR)
JANE E. HENNEY, Commissioner, U.S. Food and Drug Administration, *et al.*,	:	
Defendants	:	
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:	
Defendant-Intervenor.	:	

MEMORANDUM

The Food and Drug Administration Modernization Act of 1997 (FDAMA), codified as 21 U.S.C. § 355a, provides a 6-month extension of the statutory market exclusivity given to a new drug if, upon FDA's request, the manufacturer studies the effect of the drug on children. The plaintiffs in this case, two trade associations of generic drug manufacturers, complain that FDAMA is being misapplied. They seek to enjoin the Food and Drug Administration from granting further 6-month extensions and from issuing further written requests for pediatric studies.[1] Before the Court now is plaintiffs' application for preliminary

[1] Permissive intervention of Pharmaceutical Research and Manufacturers of America (PhRMA) as a defendant was unopposed and was granted. The motion of American Academy of Pediatrics (AAP), was opposed and will be denied for the reasons set forth below.

injunction. This memorandum sets forth reasons for the Court's findings, after a hearing, that, on the merits of their claim, plaintiffs have not demonstrated that FDA's interpretation of the statute in question is unreasonable, and that plaintiffs have not made the very strong showing of irreparable injury that would be necessary to support a preliminary injunction in view of their scant likelihood of success on the merits. The application for preliminary injunction will be denied.

FACTS

The pediatric exclusivity provision of FDAMA took effect on November 21, 1997. On March 16, 1998, in compliance with section 355a(b), FDA published a "Draft Pediatric List" of approved drugs for which it suggested that additional pediatric information might produce health benefits in the pediatric population. FDA solicited input from American Academy of Pediatrics, Pharmaceutical Research and Manufacturers of America, both plaintiffs, National Institutes of Health, Pediatric Pharmacology Research Units Network, National Association of Pharmaceutical Manufacturers (a generic trade association), and U.S. Pharmacopoeia. On May 20, 1998, within the 180-day period prescribed by section 355a(b), FDA published a final "List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population" [the

"Pediatric List"]. On July 7, 1998, the FDA issued a document entitled "Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act" [the “Guidance document”].

FDA has neither issued nor proposed regulations for implementing section 355a. It began issuing written requests for pediatric studies on specific drugs soon after publication of the Guidance document.

Plaintiffs brought this lawsuit on February 19, 1999. The complaint alleges that FDA developed the Pediatric List improperly and that FDA’s interpretation of the pediatric exclusivity provisions of Section 355a is at variance with the statute. The arguments presented at a hearing on plaintiffs’ motion for preliminary injunction held on April 9, 1999, focused mostly on plaintiffs’ objection to FDA’s position, set forth in the Guidance document and now implemented by the issuance of one or more 6-month extensions, that additional market exclusivity may be given to a manufacturer’s entire line of drug products having the same active moiety in exchange for a pediatric study conducted on only one drug product. Plaintiffs urge that such an exchange “frustrates incentives for pediatric research by conferring lucrative benefits on ‘innovator’ drug manufacturers that are completely out of proportion to the useful pediatric data generated in return.” Pl. Reply Br. at 1.

ANALYSIS

To obtain a preliminary junction, the moving party must satisfy the elements of the familiar four-part test set forth in many decisions, including CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746 (D.C. Cir. 1995).

Likelihood of success on the merits

The principal issue on the merits, as indicated above, is whether FDA has authority to grant additional exclusivity periods for drug product lines containing a single active moiety in exchange for a pediatric study covering a single drug product. The issue must be analyzed by asking the two questions mandated by Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984). The answer to the first question, "whether Congress has directly spoken to the precise question at issue," id. at 842, is a simple no. Plaintiffs attempt to argue that "the intent of Congress is clear," Pl. Reply Br. at 11-12, and that the word "drug" as used in section 355a must refer to a specific "drug product" because that is the sense in which the words is always used for New Drug Applications, Pl. Br. at 16-20. FDA responds that its interpretation of section 355a is consistent with the overall structure of regulation of generic drugs, as set forth in the Hatch-Waxman Amendments, Pub. L. 98-417, 98 Stat. 1585 (1984), which Congress knew about when it enacted FDAMA.

The main arguments of both sides focus, correctly, on the FDA's interpretation of the statute. Neither the language of section 355a nor anything in the nature of legislative history speaks directly to the question at issue.

The second, and controlling, Chevron question is whether FDA's interpretation of section 355a is "based on a permissible construction of the statute." 467 U.S. at 843. Plaintiff asserts that it is not, arguing that FDA has departed from other, consistent interpretations of the term "drug" throughout the Food Drug and Cosmetics Act to mean "drug product," Pl. Br. at 17-18, that Congress wanted extended pediatric exclusivity to be limited to the "drug product" studied in response to a request from FDA, Pl. Br. at 18-19, and that FDA's construction conflicts with the statutory purpose of maximizing information about the use of drugs in children by removing the incentive to conduct research, Pl. Br. at 19-20. There is little in the way of substantive information in this record, however, that supports these arguments. Congress did not prescribe the exact terms of the bargain it wanted struck with the research-based drug companies, leaving it to FDA to strike the appropriate balance. Absent some compelling reason why FDA's determination is not entitled to the deference normally accorded to regulatory agencies in questions of this sort, the second Chevron question must be answered, yes.

Plaintiffs present two arguments why FDA's interpretation is entitled to no deference, or to reduced deference. They argue, first, that less deference is owed to an agency's interpretation of a statute than to, say, a scientific decision. Chevron deference, however, is clearly owed to an agency's interpretation of its governing statute. See Chevron, 467 U.S. at 844 ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations.") (Citation omitted.)

Plaintiffs' second argument is that no deference is owed to an agency's interpretation of a statutory ambiguity if the agency itself has taken inconsistent opinions. Plaintiffs assert that the FDA's brief at pages 14 and 17 contradicts the Guidance document's statement that "[p]ediatric exclusivity will attach to... any drug product containing the same active moiety as the drug studied...." Pl. Br., Ex. C at 12. Just as courts may not accept as the rationale of an agency the arguments found in legal briefs, however, see Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 50 (1983), so they should not find inconsistency in an agency's rationale because of the language found in legal briefs – particularly briefs written

under the time pressure of a preliminary injunction hearing schedule.

Plaintiffs advance at least two other arguments in their briefs that were given little emphasis at the April 9 hearing. One of these arguments is that FDA acted arbitrarily and capriciously by including in the Pediatric List every drug approved for use in adults for indications that also appear in children.[2] That argument is easily resolved by appropriate deference to the expertise of FDA.

Plaintiffs further contend that the Guidance document is a "substantive" or "legislative" rule that should have been enacted through notice and comment rulemaking, pursuant to the Administrative Procedure Act, 5 U.S.C. § 553. A rule is legislative, rather than interpretive, if any one of four questions is answered in the affirmative:

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[2] FDA responds that its interest in pediatric studies of the effects in children of drugs approved for indications that appear in children is "axiomatic." Plaintiffs' reply, that the FDA argument is the post-hoc rationalization of counsel, is erroneous. The Pediatric List itself, Pl. Br., Ex. B, at 1, states:

> "After consideration of the comments, the Agency has concluded that information on any drug approved in in adults for an indication that occurs in the pediatric population may have the potential for offering a health benefit to the pediatric population. Therefore, all drugs approved by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research that are approved for use in adults for indications that occur in children are considered to be on the list."

> (1) whether in the absence of the rule there would not be an adequate legislative basis for...agency action to confer benefits or ensure the performance of duties,
> (2) whether the agency has published the rule in the Code of Federal Regulations,
> (3) whether the agency has explicitly invoked its general legislative authority, or
> (4) whether the rule effectively amends a prior legislative rule."
> American Mining Congress v. Mine Safety & Health Admin., 995 F. 2d 1106, 1112 (D.C. Cir. 1993).

Only the first question is germane in this instance, and it must be answered in the negative. The statute on its face provides all the "legislative basis" that is necessary for the agency's action.

Irreparable injury

The second factor of the four-part test is irreparable injury. "Probability of success is inversely proportional to the degree of irreparable injury evidenced." Cuomo v. United States Nuclear Regulatory Comm'n, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curiam). Here, because the likelihood of success is slim, plaintiffs would have to make a very substantial showing of severe irreparable injury in order to prevail on their motion. They have failed to do so. A 1995 report of the economic impact of GATT patent extension on currently marketed drugs establishes the general proposition that generic drug manufacturers will not realize profits from the sale of their products over the six-month periods of market exclusivity, but that effect was

obviously contemplated by Congress when it enacted FDAMA. Plaintiffs have not shown that the loss of six months would allow the creation of impenetrable barriers to market entry or cause business failures among generic manufacturers.

The public interest and harm to the parties

FDAMA has a sunset provision for the year 2002. A report is due to Congress in 2001. The legislative incentive for the conduct of important pharmaceutical testing -- which is not otherwise required of drug manufacturers -- is thus of limited duration. The injunction prayed for would prevent FDA from issuing written requests for pediatric testing. Because an FDA written request is a prerequisite of the six-month protection provided by section 355a, drug manufacturers would have no reason to initiate testing during the pendency of an injunction. The public interest would be disserved by an injunction whose operation would be to remove the incentive for testing or actually to stop new testing. As for harm to the parties, it is true that generic drug manufacturers have something to lose and innovator drug manufacturers something to gain from the denial of a preliminary injunction, but that equation was set in place by the enactment of FDAMA.

Intervention

The motion of American Academy of Pediatrics (AAP) to intervene of right will be denied, although AAP claims an interest relating to the "transaction which is the subject of the action," Fed. R. Civ. P. 24(a), and although AAP arguably has standing. AAP's brief and oral argument were fully considered by the Court and contributed to the Court's understanding of the public's interest in providing incentives for pediatric studies of new drugs. But AAP's interest is adequately represented by existing parties.

An appropriate order accompanies this memorandum.

_____
JAMES ROBERTSON
United States District Judge

DATE:_____

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ORDER

Upon consideration of the entire record, it is this ____ day of April 1999

ORDERED that plaintiffs' motion for a preliminary injunction [# 3] is **denied**. It is

FURTHER ORDERED that the motion of the American Academy of Pediatrics' motion to intervene as a defendant [# 8] is **denied**.

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JAMES ROBERTSON
United States District Judge

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